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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/716,029	11/17/00	CHEN F	6200-0013

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EXAMINER
KWON, B

ART UNIT	PAPER NUMBER
1614	5

DATE MAILED: 07/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/716,029	CHEN ET AL.	
	Examiner	Art Unit	
	Brian-Yong S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 37-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 37-51* is/are rejected.

7)☒ Claim(s) *37-49 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1,4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

Claims 37-49 and 51 are objected because they are depended upon on non-elected claims 13-36. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite by reciting "treating a patient who would benefit from...". It is not clear what is the scope of the claimed invention. Does applicant mean "treating any conditions, diseases or disorders" described in column 23, lines 19-22 of the instant disclosure? Or meaning treatment of the specific lipid disorders. Applicant is requested to clarify and appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 37, 41-44 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Edgar et al. (US 5880148).

Edgar et al. teaches a synergistic combination of 33-200mg of fenofibrate and 100-600mg of a vitamin E substance (i.e., dl-α-tocopherol acetate) solution, in the form of gelatin capsule, for treating and preventing of pathological conditions including atheromatous disease, diabetes, arterial hypertension, and restenosis (see column 4, lines 25-30 and 38-67).

It is noted that recitations of inherent property such as the use of a vitamin E substance as a solubilizer are not limited to the interpretation of composition claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-12 and 38-40, 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edgar et al. (US 5880148) in view of Patel et al. (US 6248363 B1).

The claims read on a pharmaceutical composition for oral administration of hydrophobic drug comprising fenofibrate and a solubilizer such as a vitamin E substance, a trialkyl citrate, a lactone, a nitorgen-containing solvent or combination thereof.

The teaching of Edgar et al. has been already discussed in above 102(b) rejection.

Patel et al. teaches/suggests the use of a trialkylcitrate (i.e., tributylcitrate, acetyl triethylcitrate, acetyl tributyl citrate, triethylcitrate, etc...), a lactone (i.e., ε-caprolactone and isomers thereof, δ-valerolactone and isomers thereof, β-butyrolactone and isomers thereof, etc...) and a nitrogen-containing solvent (i.e., N-alkypyrrolidone, N-alkypiperidone, dimethylacetamide, N-alkylcaprolactam, N-hydroxyalkypyrrolidone, etc...) as a solubilizer to increase the solubility of the hydrophobic active ingredient such as fenofibrate. See column 7, line 35 as well as from column 37 line 25 to column 38 line 22.

The teaching of Edgar et al. differs from the claimed invention in the use of a trialkyl citrate, a lactone or a nitrogen-containing solvent as a solubilizer for the hydrophobic active ingredient such as fenofibrate and the range of solubilization concentration of said active ingredient in said composition. To incorporate such teaching into the teaching of Edgar et al.,

would have been obvious in view of Patel et al. who teaches the use of said solubilizers to increase the solubility of the pharmaceutical active ingredient such as fenofibrate. One having ordinary skill in the art would have been motivated to do so such that the bioavailability of hydrophobic drug could be improved or the concentration of the hydrophobic active ingredient such as fenofibrate could be maximized. One having ordinary skill in the art would have expected that the determination of solubilization concentration of said active ingredient in said composition would have been within the skill of the artisan. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Additionally, the determination of dosage form such as a semi-liquid form or a drink form having optimum therapeutic index is well considered within the skill of the artisan, absent evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600